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(54) **PELVIC IMPLANT NEEDLE SYSTEM AND METHOD**

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See application file for complete search history.

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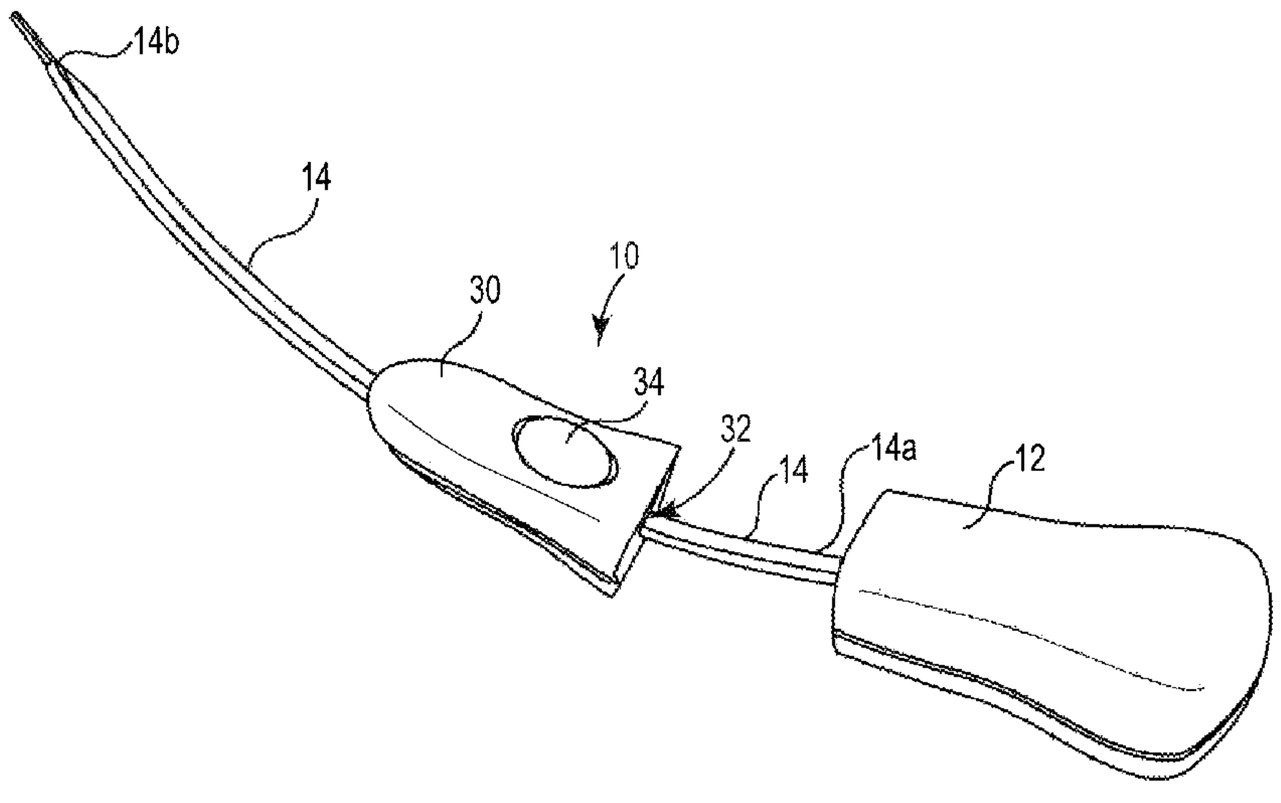
(57) **ABSTRACT**

Various embodiments of a trocar or needle system for use in inserting and deploying pelvic implants are provided. The needle device can include a solid or hollow shaft portion with a non-circular cross-section. A grip element can be provided to slide along a length of the needle shaft to further facilitate handling.

20 Claims, 4 Drawing Sheets



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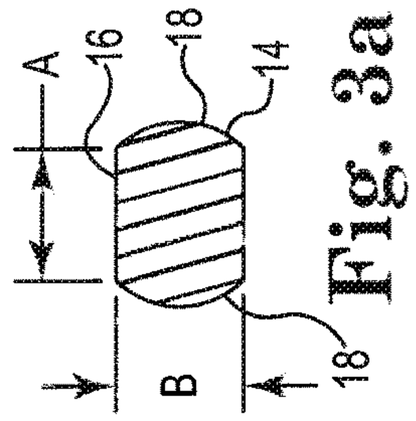


Fig. 3a

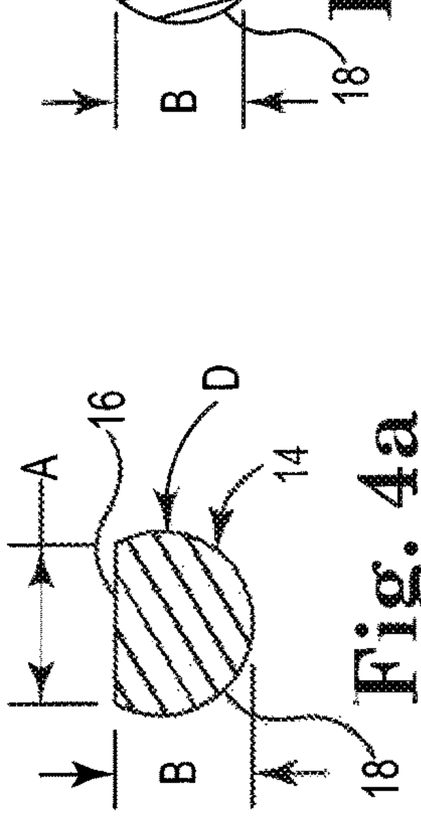


Fig. 4a

Fig. 1

Fig. 3b

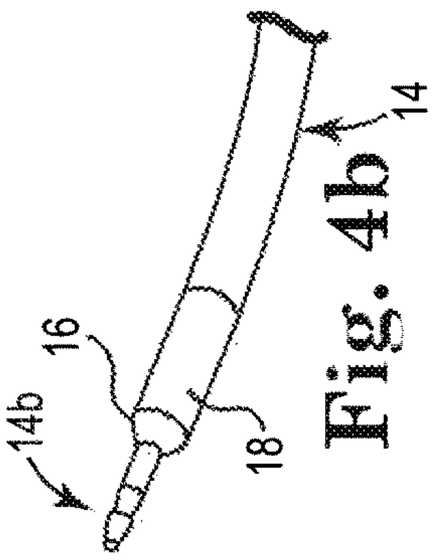


Fig. 4b

Fig. 2

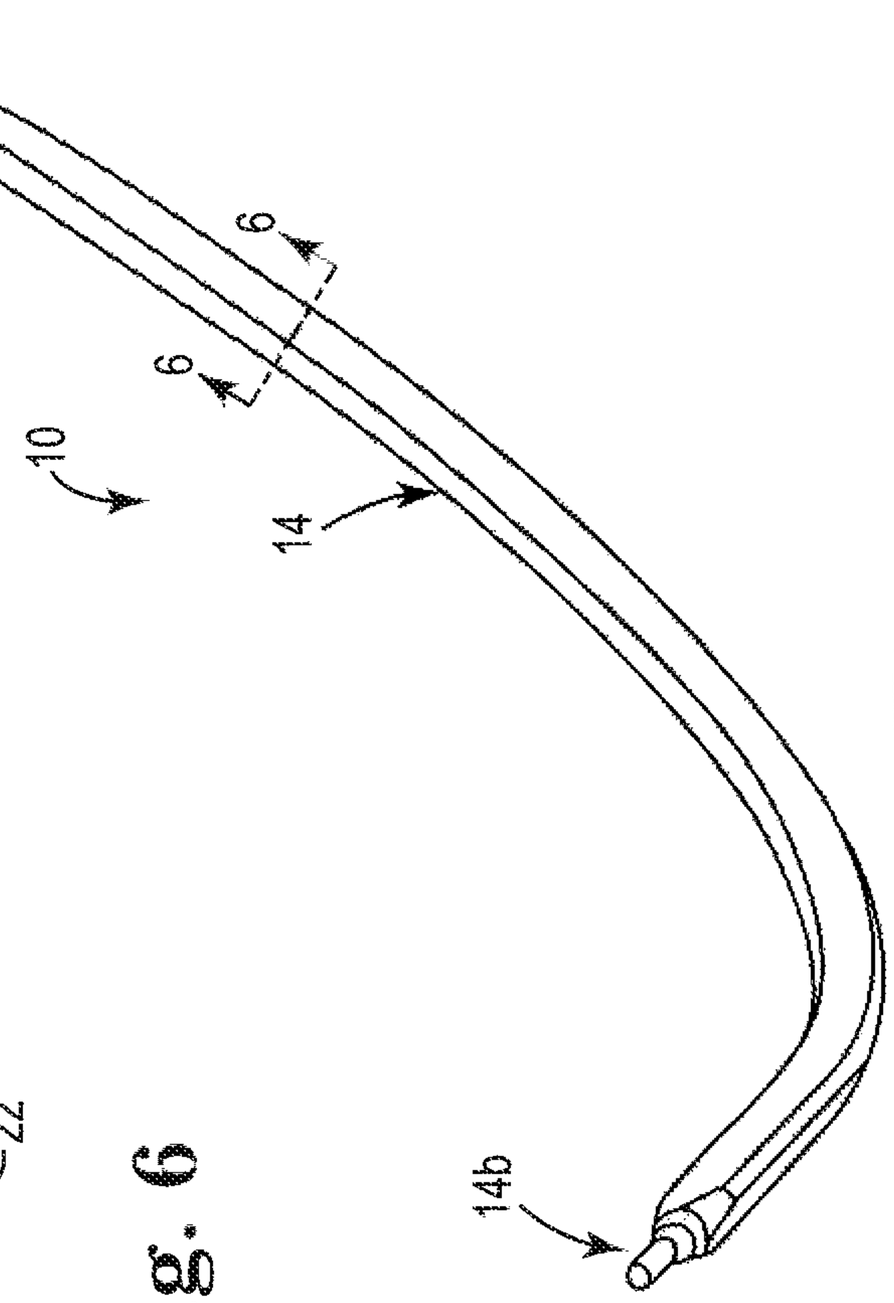


Fig. 5

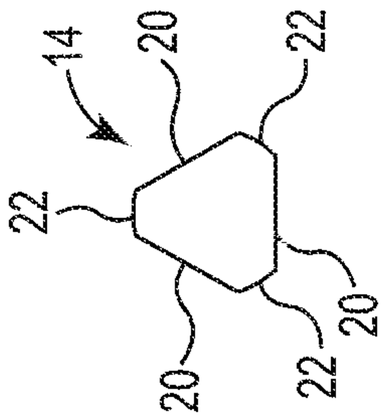
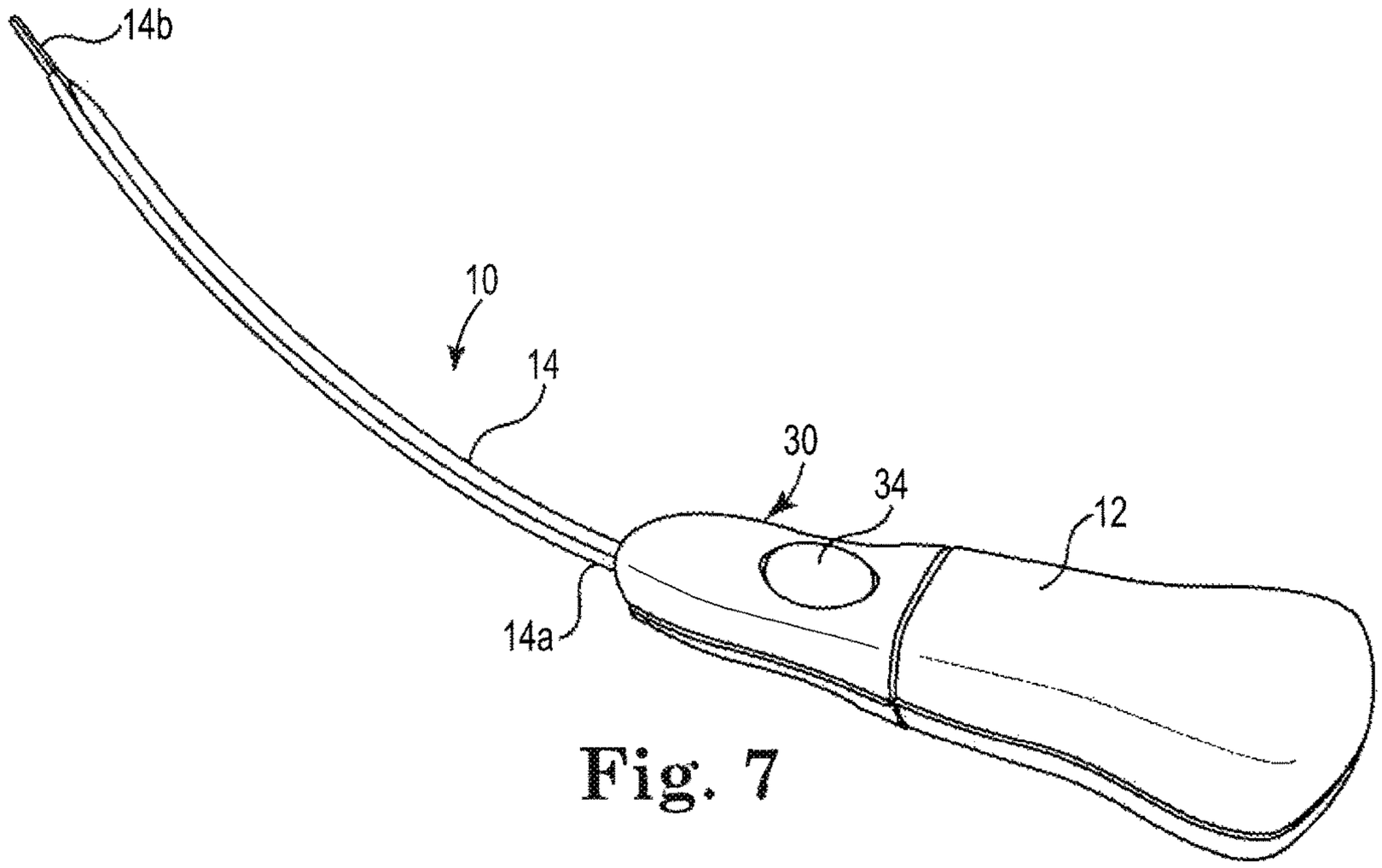


Fig. 6



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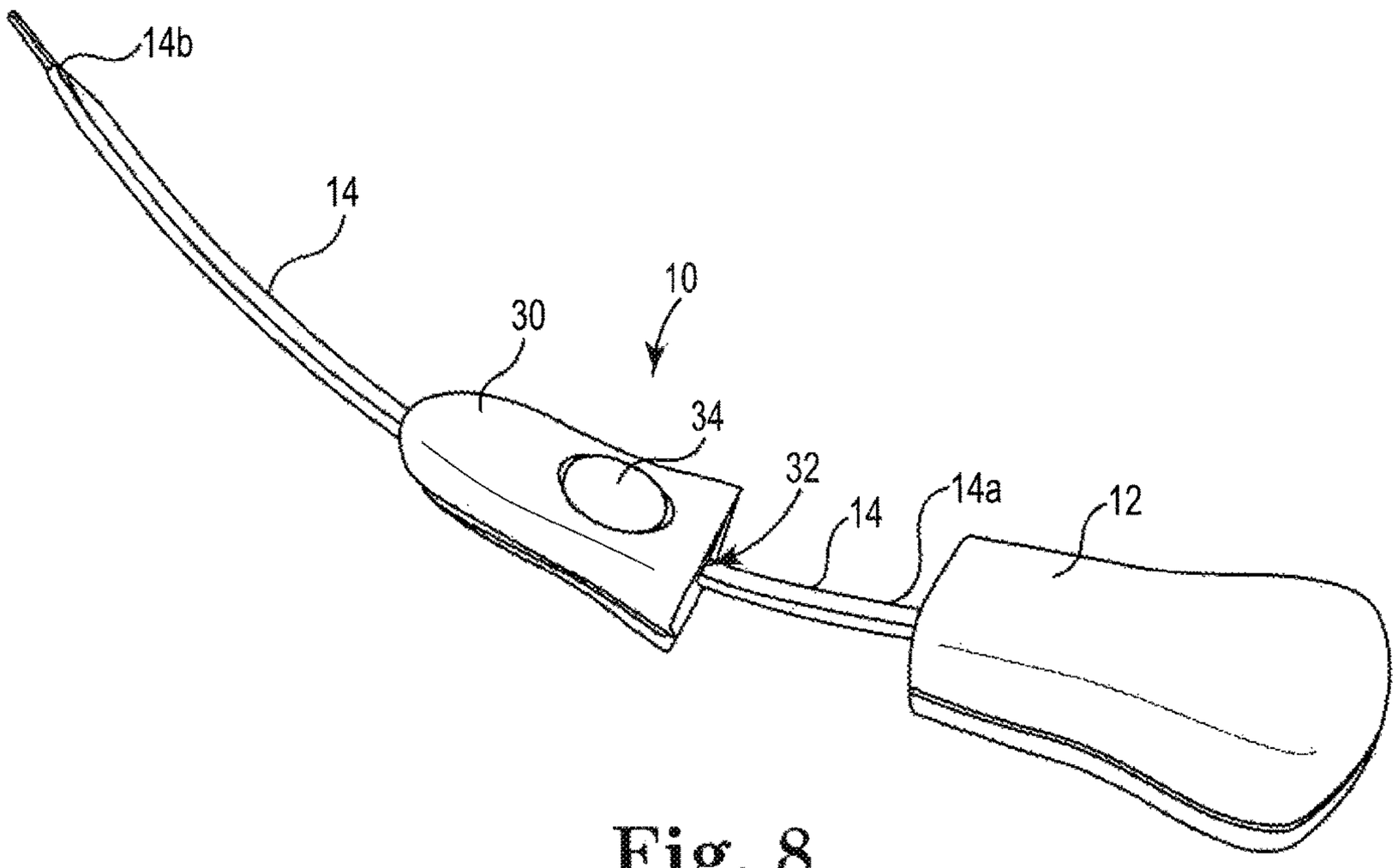

Fig. 8

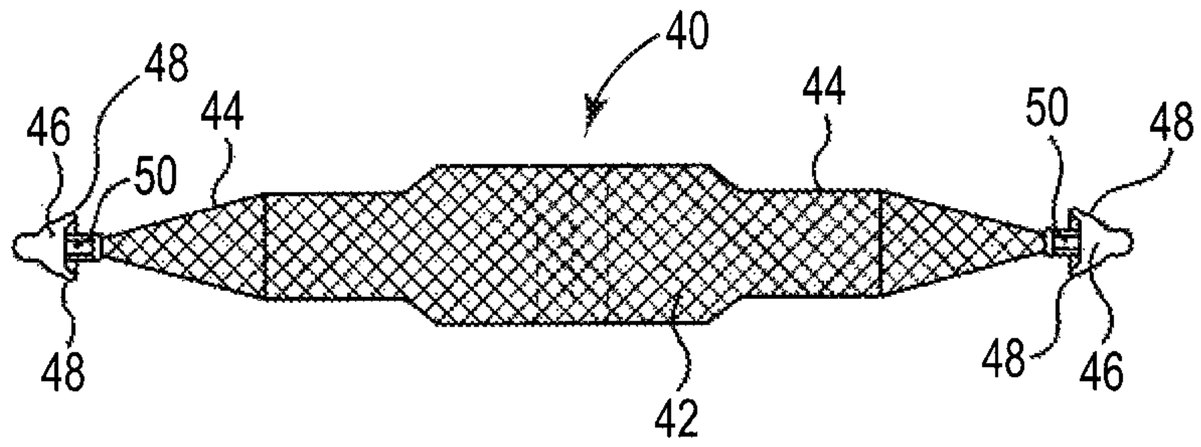

Fig. 9

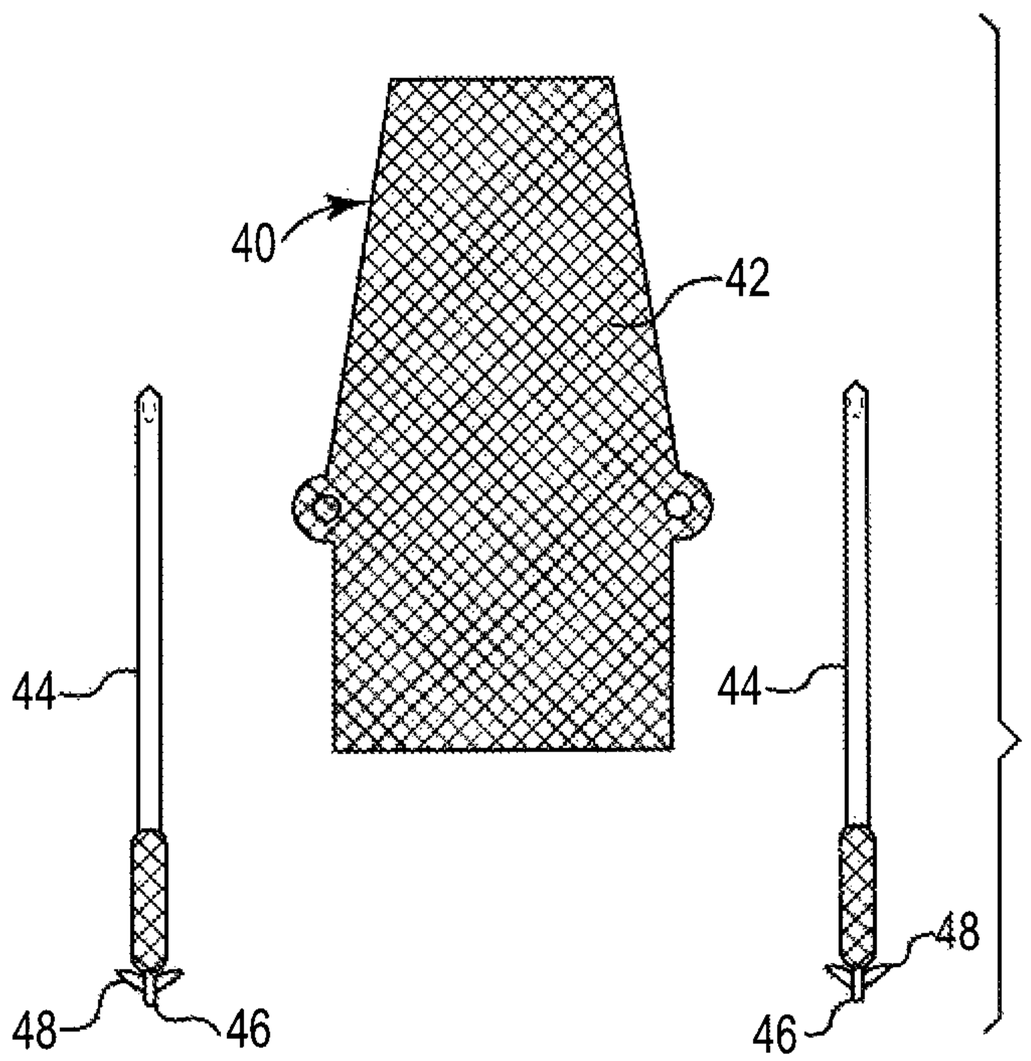

Fig. 10

PELVIC IMPLANT NEEDLE SYSTEM AND METHOD

PRIORITY

This Application claims priority to and the benefit of U.S. Provisional Patent Application No. 61/530,380, filed Sep. 1, 2011, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

The present invention relates generally to surgical methods and apparatus and, more specifically, to surgical trocar or needle devices used for introducing and deploying an implant or sling to treat incontinence or other pelvic disorders.

BACKGROUND OF THE INVENTION

Pelvic health for men and women is a medical area of increasing importance, at least in part due to an aging population. Examples of common pelvic ailments include incontinence (e.g., fecal and urinary), pelvic tissue prolapse (e.g., female vaginal prolapse), and conditions of the pelvic floor.

Urinary incontinence can further be classified as including different types, such as stress urinary incontinence (SUI), urge urinary incontinence, mixed urinary incontinence, among others. Other pelvic floor disorders include cystocele, rectocele, enterocele, and prolapse such as anal, uterine and vaginal vault prolapse. A cystocele is a hernia of the bladder, usually into the vagina and introitus. Pelvic disorders such as these can result from weakness or damage to normal pelvic support systems.

Urinary incontinence can be characterized by the loss or diminution in the ability to maintain the urethral sphincter closed as the bladder fills with urine. Male or female stress urinary incontinence (SUI) generally occurs when the patient is physically stressed.

In its severest forms, vaginal vault prolapse can result in the distension of the vaginal apex outside of the vagina. An enterocele is a vaginal hernia in which the peritoneal sac containing a portion of the small bowel extends into the rectovaginal space. Vaginal vault prolapse and enterocele represent challenging forms of pelvic disorders for surgeons. These procedures often involve lengthy surgical procedure times.

Urinary incontinence can be characterized by the loss or diminution in the ability to maintain the urethral sphincter closed as the bladder fills with urine. Male or female stress urinary incontinence (SUI) occurs when the patient is physically stressed.

There is a desire to obtain a minimally invasive yet highly effective implant and introduction system that can be used to treat incontinence, and/or pelvic organ prolapse and other conditions.

SUMMARY OF THE INVENTION

The present invention describes an implant or sling insertion needle or trocar system, device and method. While typical trocars can include a curved stainless steel needle to create a pathway for a supporting mesh sling, embodiments of the present needle device can include a solid or hollow needle shaft portion with a non-circular cross-section. The use of a non-circular form for the needle provides distinct functional advantages.

Namely, a needle device having a non-circular cross-section needle shaft can provide improved visual and tactile feedback pertaining to the orientation of the needle, better gripping control of the needle, and improved finger contact surfaces to reduce finger pressure and slippage.

Embodiments can include a needle device having a housing or grip element. The grip can be constructed of a rigid plastic material, suitably shaped for gripping by the physician's fingers. The grip element can include flats, curved portions, holes, a through-aperture or other constraining means by which it may be slidably attached to the needle. In certain embodiments, for instance, the through-aperture is shaped and sized to generally match the shape and size of the needle, e.g., non-circular cross-section. As such, the grip element can slide along a longitudinal length of the non-circular cross-section needle, while still restricting rotational movement about the needle shaft. A mechanism can be included with the element, e.g., button or actuator, to selectively stop sliding of the element along the needle when desired. The mechanism allows the physician to apply both axial and rotational loads on the needle.

The needles described and depicted herein can be employed in treating pelvic conditions such as incontinence (various forms such as fecal incontinence, stress urinary incontinence, urge incontinence, mixed incontinence, etc.), vaginal prolapse (including various forms such as enterocele, cystocele, rectocele, apical or vault prolapse, uterine descent, etc.), and other conditions caused by muscle and ligament weakness. Implants utilized with the system can include a tissue support portion and one or more anchors, arms and the like.

Embodiments of the present invention may be incorporated into or provided with various commercial products marketed by American Medical Systems of Minnetonka, Minn., as the MiniArc® Single-Incision Sling and like implant or anchoring systems.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic view of a non-circular, generally elliptical, needle device, in accordance with embodiments of the present invention.

FIG. **2** is a schematic cross-sectional view of the non-circular, generally elliptical, needle device of FIG. **1**, in accordance with embodiments of the present invention.

FIG. **3** is a schematic view of a non-circular needle device, with flat and curved portions, in accordance with embodiments of the present invention.

FIG. **3***a* is a schematic cross-sectional view of the non-circular needle device of FIG. **3**, in accordance with embodiments of the present invention.

FIG. **3***b* is a partial schematic view of a non-circular needle device, with flat and curved portions, in accordance with embodiments of the present invention.

FIG. **4** is a schematic view of a non-circular needle device, with flat and curved portions, in accordance with embodiments of the present invention.

FIG. **4***a* is a schematic cross-sectional view of the non-circular needle device of FIG. **4**, in accordance with embodiments of the present invention.

FIG. **4***b* is a partial schematic view of a non-circular needle device, with flat and curved portions, in accordance with embodiments of the present invention.

FIG. **5** is a schematic view of a non-circular trilobe needle device, in accordance with embodiments of the present invention.

FIG. **6** is a schematic cross-sectional view of the non-circular trilobe needle device of FIG. **5**, in accordance with embodiments of the present invention.

FIG. **7** is a schematic view of a needle device having a needle shaft, handle and slidable grip element, in accordance with embodiments of the present invention.

FIG. **8** is a schematic view of a needle device having a needle shaft, handle and slidable grip element slid a distance along a length of the shaft, in accordance with embodiments of the present invention.

FIGS. **9-10** are schematic views of pelvic implant devices for use with needle devices, in accordance with embodiments of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring generally to FIGS. **1-10**, various embodiments of a trocar or needle device **10** are shown. The needle device **10** described and depicted herein can be employed in introducing or deploying implants used to treat pelvic conditions such as incontinence (various forms such as fecal incontinence, stress urinary incontinence, urge incontinence, mixed incontinence, etc.), vaginal prolapse (including various forms such as enterocele, cystocele, rectocele, apical or vault prolapse, uterine descent, etc.), and other conditions caused by muscle and ligament weakness. Implants utilized with the system can include a tissue support portion and one or more anchors, arms and the like, as disclosed herein.

The needle devices **10** can include a handle portion **12** and a needle portion **14**. The needle portion **14** can be curved, straight, helical, and the like. The needle portion **14** can include a proximal portion **14***a* and a distal tip portion **14***b*. The proximal portion **14***a* can be operatively connected to the handle portion **12**.

The needle **14** of the present invention can include a solid or hollow shaft with a non-circular cross-section. The use of a non-circular form for the needle **14** provides distinct functional advantages. Namely, a non-circular cross-section needle **14** provides improved visual and tactile feedback pertaining to the orientation of the needle, better gripping control of the needle, and improved finger contact surfaces to reduce finger pressure and slippage. In addition, defined flat or angular surfaces along portions of the needle **14** shaft can provide a desirable construct to restrict rotation of any device or mechanism adapted to slide along a length of the needle **14**.

Referring generally to FIGS. **1-6**, the non-circular form of the needle **14** can take on numerous shapes and configurations. For instance, in one embodiment, the cross-section can be generally elliptical, as shown in FIGS. **1-2**. Such a generally elliptical structure can be defined by a horizontal dimension A and a vertical dimension B. In certain embodiments, dimension A can be defined in a range of approximately 0.150 inches to 0.200 inches, with dimension B defined in a range of approximately 0.100 inches and 0.150 inches. Other dimensional characteristics can be employed with various embodiments without deviating from the spirit and scope of the present invention.

As shown in FIGS. **3-4***b*, embodiments of the needle **14** can include one or more flat portions **16** and one or more curved portions **18** to define the non-circular needle cross-section. The one or more curved portions **18** can be generally concave, convex, or a combination thereof. The one or more flat portions **16** can facilitate and promote contact and stability for the physician's finger to provide orientation feedback and granular control. The flat portions **16** can face either toward the inside or outside of the needle bend, for those embodiments having a curved needle **14**. The horizontal portion A can be defined in a range of approximately 0.150 inches to 0.175 inches, with the vertical dimension B defined in a range of approximately 0.125 inches to 0.150 inches. Again, other dimensional characteristics can be employed with various embodiments without deviating from the spirit and scope of the present invention. FIGS. **4-4***b* depict an embodiment having a single flat portion **16** and a larger single curved portion **18**, e.g., 0.175 inch to 0.200 inch diameter D. FIGS. **3-3***b* show an embodiment having two opposing flat portions **16** and two opposing curved portions **18**. The flat portions **16** can be approximately 0.125 inches to 0.140 inches in length, with the vertical dimension B ranging approximately between 0.120 inches and 0.140 inches. Again, other dimensional characteristics, proportions and shapes are envisioned for various embodiments.

FIGS. **5-6** show an embodiment of the needle **14** having a generally trilobe configuration or cross-section. The trilobe configuration can be defined by three primary linear portions **20**. In certain embodiments, the linear portions **20** are in direct communication to define a generally triangular shape. In other embodiments, as shown in FIG. **6**, one or more secondary portions **22** extend between the linear portions **20**. The secondary portions **22** can be generally linear or curved. For those embodiments having generally curved portions **22** the diameter D measurement for one or more of the portions **22** can range from approximately 0.175 inches to 0.190 inches. Again, other dimensional characteristics are envisioned for use as well. These various trilobe embodiments can provide a desirable tactile feedback and control structure for the needle **14** as well.

Other triangular, rectangular, octagonal, hectagonal, pentagonal, and like shapes and constructs, including other polygon shapes, can be implemented to achieve one or more non-circular needle **14** cross-sections to facilitate the objectives and advantages described herein.

FIGS. **7-8** show and describe various exemplary use applications for the needle device **10** having a housing or grip element **30**. Again, the needle **14** can be connected to the handle **12**. In certain embodiments, the grip **30** is constructed of a rigid plastic material, suitably shaped for gripping by the physician's fingers and/or hand. The outer portions of the grip **30** can include various surface textures or features to further facilitate handling and gripping.

The grip element **30** can include flats, curved portions, holes, a through-aperture **32** or other constraining means by which it may be slidably attached to the needle **14**. In certain embodiments, for instance, the through-aperture **32** is shaped and sized to generally match the shape and size of the needle **14** (except it can be measurably larger to permit sliding along the needle **14**), e.g., non-circular cross-section. As such, the grip element **30** can slide along a longitudinal length of the non-circular cross-section needle **14**, while still restricting rotational movement about the needle shaft. A mechanism **34** can be included with the housing **30**, e.g., button or actuator, to selectively stop sliding of the element **30** along the needle **14** when desired. The mechanism **34** can be a stop member, ratchet mechanism, a friction feature or element or like mechanism operatively connected with the mechanism **34**. Such a mechanism **34** can be in operative communication with a rubber member or element adapted for selective engagement with the needle shaft. The mecha-

nism **34** allows the physician to apply both axial and rotational loads on the needle **14** during implant introduction or deployment.

In certain embodiments, the grip element **30** can be employed with a needle **14** having a generally circular cross-section. Further, various embodiments of the mechanism **34** can be initially biased or engaged with the needle to restrict sliding of the grip **30** along the needle **14** until the mechanism **34** is actuated or released.

To use the device **10**, a physician or end user actuates or releases the mechanism **34** to permit slidable repositioning of the element **30** along the needle **14**. When at the desired position, the stop mechanism **34** is re-engaged, or released, to allow the physician to apply both axial and rotation loads to the needle **14**. This element **30** can be particularly useful with "top-down" or like retropubic needle passes in which the physician commonly manipulates the needle **14** directly rather than via the handle **12**.

Alternatively, the element **30** can serve as a bearing surface particularly useful when passing a needle through the anatomical structure during a "bottom-up" implantation procedure. With the mechanism **34** disengaged, the device **10** may be held in one hand while the other hand is free to push the needle from the handle. With curved needles **14**, this allows the needle to advance along its curved shape without pushing into or dragging along the hand holding the needle.

As shown in FIGS. **9-10**, various embodiments of implantable sling or mesh devices **40** and methods adapted to include certain anchoring and other implant structures or devices are disclosed herein for use with the present invention. In general, the implant devices **40** can include a support portion **42**, and extension or arm portions **44** having anchors **46** provided therewith. Various anchor **46** embodiments provided herein can include one or more extending tines or barbs **48** to promote tissue engagement and fixation. An aperture or other engagement portion **50** can be included with the device **40**, e.g., the anchors **46**, and adapted to selectively or releasably engage with the device **10**, e.g., the needle tip **14***b*. Various portions of the implant device **40** can be constructed of polymer materials from a mesh of filaments. Certain embodiments can be constructed of or from a film or sheet material of polypropylene, polyethylene, fluoropolymers or like compatible materials.

The various implants **10** or systems, features and methods detailed herein are envisioned for use with many known implant and repair systems (e.g., for male and female), features and methods, including those disclosed in U.S. Pat. Nos. 7,500,945, 7,407,480, 7,351,197, 7,347,812, 7,303,525, 7,025,063, 6,691,711, 6,648,921, and 6,612,977, International Patent Publication Nos. WO 2008/057261 and WO 2007/097994, and U.S. Patent Publication Nos. 2012/0157761, 2011/0144417, 2011/0124956, 2010/0105979, 2002/151762 and 2002/147382. Accordingly, the above-identified disclosures are fully incorporated herein by reference in their entirety.

The implant systems, tools, devices, their various components, structures, features, materials and methods may have a number of suitable configurations as shown and described in the previously-incorporated references. Various methods and tools for introducing, deploying, anchoring and manipulating implants to treat incontinence and prolapse as disclosed in the previously-incorporated references are envisioned for use with the present invention as well. Further, the systems, devices, device portions, components or structures disclosed herein can be constructed of compatible materials know to those skilled in the art, including metals, polymers, and the like.

All patents, patent applications, and publications cited herein are hereby incorporated by reference in their entirety as if individually incorporated, and include those references incorporated within the identified patents, patent applications and publications.

Obviously, numerous modifications and variations of the present invention are possible in light of the teachings herein. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

The invention claimed is:

1. An implant introduction system, comprising:

an implant introduction device, including;

a handle portion having a proximal portion and a distal portion, and a first side and a second side in which a distance between the first side and the second side defines a width;

a needle having a distal tip portion, a shaft portion, and a proximal portion operatively connected to the distal portion of the handle portion, the distal tip portion having a cross-sectional shape that is smaller than a cross-sectional shape of the shaft portion;

wherein the shaft portion has a non-circular cross-section;

an elongate grip device having a proximal end and a distal end defining a grip length, and a first side and a second side in which a distance between the first side and the second side defines a width, the width of the grip device being smaller than the width of the handle portion, the grip device configured to slide along a length of the shaft portion of the needle relative to the handle portion such that the proximal end of the grip device is slidable away from and abuttable with the handle portion, the grip device having a side gripping feature, and a manual actuation mechanism recessed within the grip device, provided substantially flush with an outer surface of the grip device, and adapted to selectively limit sliding of the grip device along the shaft portion; and

an implant device including a mesh implant having a first end portion and a second end portion, the implant device including an anchor coupled to the first end portion of the mesh implant, the anchor including a distal end portion having one or more barbs configured to engage with tissue, the anchor including proximal end portion defining an aperture, the aperture of the proximal end portion of the anchor configured to selectively receive the distal tip portion of the needle.

2. The system of claim **1**, wherein the non-circular cross-section of the shaft portion is generally elliptical.

3. The system of claim **1**, wherein the non-circular cross-section of the shaft portion includes one or more flat portions.

4. The system of claim **3**, wherein the non-circular cross-section of the shaft portion includes one or more curved portions.

5. The system of claim **1**, wherein the non-circular cross-section of the shaft portion defines a trilobe cross-section.

6. The system of claim **1**, wherein the cross-sectional shape of the distal tip portion is different than the cross-sectional shape of the shaft portion.

7. The system of claim 1, wherein the shaft portion is a curved shaft, the curved shaft having a first side and a second side opposite to the first side, the first side being flat, the second side being curved.

8. The system of claim 1, wherein at least the shaft portion of the needle is constructed of metal.

9. The system of claim 1, wherein at least a length of the shaft portion of the needle is curved.

10. The system of claim 1, wherein the shaft portion has a curve defining a bend, the curved shaft having a first side extending a majority of a length of the needle, and a second side extending a majority of a length of the needle, the second side being opposite to the first side, the first side being flat and facing towards an inside of the bend, the second side being curved and facing toward an outside of the bend.

11. A needle introduction device, comprising:

a fixed handle portion having a proximal portion and a distal portion, and a first side and a second side in which a distance between the first side and the second side defines a width;

a needle having a distal tip portion, a shaft portion, and a proximal portion operatively connected to the distal portion of the handle portion, the shaft portion having a non-circular cross-section, the distal tip portion having a cross-sectional shape that is smaller than a cross-sectional shape of the shaft portion;

an elongate grip portion having a distal portion, a proximal portion, a first side, and a second side, in which a distance between the first side and the second side defines a width, the width of the grip portion being smaller than the width of the handle portion, the grip portion configured to slide along a length of the shaft portion such that the proximal portion is abuttable against the fixed handle portion, the grip portion having a side gripping feature, and a generally flush button mechanism, recessed within the grip portion, and adapted to selectively limit sliding of the grip portion along the shaft portion; and

an implant device including a mesh implant having a first end portion and a second end portion, the implant device including an anchor coupled to the first end portion of the mesh implant, the anchor including a distal end portion having one or more barbs configured to engage with tissue, the anchor including proximal end portion defining an aperture, the aperture of the proximal end portion of the anchor configured to selectively receive the distal tip portion of the needle.

12. The device of claim 11, wherein the non-circular cross-section of the shaft portion is generally elliptical.

13. The device of claim 11, wherein the non-circular cross-section of the shaft portion includes one or more flat portions.

14. The device of claim 13, wherein the non-circular cross-section of the shaft portion includes one or more curved portions.

15. The device of claim 11, wherein the non-circular cross-section of the shaft portion defines a trilobe cross-section.

16. The device of claim 11, wherein the handle has a handle abutment portion having a peripheral edge, and the grip portion has a grip abutment portion having a peripheral edge substantially matching a size and shape of the peripheral edge of the handle abutment portion.

17. The device of claim 16, wherein the shaft portion is a curved shaft, the curved shaft having a first side and a second side opposite to the first side, the first side being flat, the second side being curved.

18. The device of claim 11, wherein the grip portion includes a non-circular through-aperture adapted to substantially match the non-circular cross-section of the shaft portion.

19. The device of claim 11, wherein at least a length of the shaft portion of the needle is curved.

20. A needle introduction device, comprising:

a fixed handle portion having a proximal portion and a distal portion;

a needle having a distal tip portion, a shaft portion, and a proximal portion operatively connected to the distal portion of the handle portion, the shaft portion having a non-circular cross-section, the distal tip portion having a cross-sectional shape that is smaller than a cross-sectional shape of the shaft portion,

wherein the shaft portion has a curve defining a bend, the curved shaft having a first side extending a majority of a length of the needle, and a second side extending a majority of a length of the needle, the second side being opposite to the first side, the first side being flat and facing towards an inside of the bend, the second side being curved and facing toward an outside of the bend;

an elongate grip portion having a distal portion, a proximal portion, and adapted to slide along a length of the shaft portion such that the proximal portion is abuttable against the fixed handle portion, the grip portion having a side gripping feature, and a generally flush button mechanism, recessed within the grip portion, and adapted to selectively limit sliding of the grip portion along the shaft portion; and

an implant device including a mesh implant having a first end portion and a second end portion, the implant device including an anchor coupled to the first end portion of the mesh implant, the anchor including a distal end portion having one or more barbs configured to engage with tissue, the anchor including proximal end portion defining an aperture, the aperture of the proximal end portion of the anchor configured to selectively receive the distal tip portion of the needle.

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